

REMARKS

Claims 41-53 are currently pending. With this response, new claim 54 has been added. Support for new claim 54 can be found, *e.g.*, in paragraph [0053] of the published application (U.S. 2006/0121480). As such, new claim 54 does not constitute new subject matter. Therefore, upon entry of this Amendment, claims 41-54 will be pending. Applicant requests consideration and entry of the amendments and remarks into the record.

I. The Rejections For Obviousness Should Be Withdrawn

Claims 41-53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson, *et al.* (U.S. Patent No. 6,475, 491, “Johnson”) and Hanna, *et al.* (U.S. Patent No. 6,136,310, “Hanna”). The Examiner alleges that Johnson provides combination therapies employing HIV-1 fusion inhibitors, *e.g.*, T20, as well as other antiviral agents and that Hanna discloses the preparation of anti-CD4 antibodies useful as therapeutic agents. As such, the Examiner contends that the claimed methods would have been obvious in view of the combination of Johnson and Hanna.

For the reasons set forth below, Applicant respectfully disagrees, and request the Examiner’s reconsideration of the rejection of claims 41-53 as obvious over Johnson and Hanna.

A. The Legal Standard

A finding of obviousness requires that “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. §103(a).

In its recent decision addressing the issue of obviousness, *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007), the Supreme Court stated that the following factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) still control an obviousness inquiry: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *KSR*, 127 S.Ct. at 1734, 82 USPQ2d at 1388 quoting *Graham*, 383 U.S. at 17-18, 14 USPQ at 467. The relevant inquiry is whether the prior art suggests the invention and whether the prior art provides one of ordinary skill in the art with a

reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). Finally, evidence of unexpected or unobvious results is objective evidence of nonobviousness, and may be used to rebut a *prima facie* case of obviousness. *In re Wagner*, 371 F.2d 877 (C.C.P.A. 1967); M.P.E.P. § 716.02.

B. The Claimed Invention is Nonobvious over Johnson and Hanna

Applicant asserts that one of skill in the art would not have been motivated to combine Johnson with Hanna with the expectation of successfully arriving at the claimed method for preventing infection of target cells by human immunodeficiency virus (HIV) type 1 comprising exposing said target cells to a combination of a viral attachment inhibitor and a viral fusion inhibitor, nor would one expect that such a combination would have a synergistic effect on the inhibition of HIV infection.

Johnson provides that the preferable antiviral agents to be used in conjunction with the viral fusion inhibitors disclosed (one of such viral fusion inhibitors being pentafuside) include an effective amount of AZT or ddI (*see*, Johnson at col. 17, *ll.* 21-27). Johnson further provides an exhaustive list of other possible antiviral agents, such as uridine phosphorylase inhibitors, cytokines, cytokine inhibitors, viral protease inhibitors, agents that interfere with 5'-mRNA processing, and inhibitors of glycoprotein processing (*see*, Johnson at col. 17, *l.* 28 to col. 18, *l.* 53). However, Johnson does not indicate that attachment inhibitors should be used along with inhibitors that would prevent viral entry, such as fusion inhibitors. In fact, Johnson makes no mention whatsoever of attachment inhibitors.

Hanna, alone or in combination with Johnson, does not cure the deficiencies of Johnson. Hanna identifies chimeric antibodies specific to human CD4 antigen and suggests their use as therapeutics in CD4-related disorders, in particular, autoimmune disorders and other conditions where immunosuppression is desirable (*see*, Hanna, col. 6, *ll.* 6-19). According to Hanna, the chimeric CD4 antibodies may be used to treat a long list of disorders including, rheumatoid arthritis, leukemia lymphoma, graft-versus-host disease, transplant rejection and HIV (*see*, Hanna, at col. 11, *ll.* 45-54). Hanna suggests that the chimeric anti-CD4 antibodies most likely have therapeutic utility by arresting activity of CD4+ cells, thereby resulting in a state of immunological unresponsiveness or long term tolerance to insulting antigens (*see*, Hanna, at col. 11, *ll.* 33-45). Given the proposed mechanism of action for the disclosed CD4 antibodies as immunosuppressors, it is unclear how an antibody that works to suppress the immune system

would have utility as an HIV therapeutic. Certainly, there is nothing in Hanna to suggest that the anti-CD4 antibodies have utility as attachment inhibitors, *i.e.*, inhibiting HIV attachment with target cells. Furthermore, Hanna never suggests combining an HIV attachment inhibitor and an HIV fusion inhibitor in any form. In fact, Hanna makes no mention whatsoever of fusion inhibitors.

Applicant asserts that at the time of filing of the instant invention, there is no reason one of ordinary skill in the art would have been motivated to combine Hanna and Johnson to arrive at the instant invention. First, Johnson does not provide any suggestion that the disclosed fusion inhibitors should be combined with attachment inhibitors. Rather, Johnson suggests generically that their fusion inhibitors be used in combination with inhibitors of viral replication, such as nucleoside inhibitors, cytokine inhibitors, and inhibitors of 5'-mRNA processing. Second, Hanna does not describe or suggest fusion inhibitors or combination therapy as a means to treat HIV infection and further it is difficult to conceive a use for the immunosuppressive antibodies taught by Hanna in HIV therapy.

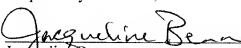
In view of the arguments above, Applicant asserts that it would not have been obvious to one of ordinary skill in the art to combine the teachings of Johnson with Hanna to come up with the instantly claimed invention. Therefore, Applicant respectfully requests that the rejection of claims 41-53 under 35 U.S.C. § 103(a), for obviousness, be withdrawn.

CONCLUSION

Applicant respectfully requests entry and consideration of the foregoing amendments and remarks. Withdrawal of the rejection and an allowance are earnestly sought.

Respectfully submitted,

Date: July 2, 2008


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